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12M2/0929

EXAMINER	
RUTMAN, A	
ART UNIT	PAPER NUMBER
1203	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/809,224	Applicant(s) Karen R.Romines et al.
	Examiner Alan L.Rotman	Group Art Unit 1203

Responsive to communication(s) filed on _____.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-39 is/are pending in the application.

Of the above, claim(s) 23-37 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-21, 38, and 39 is/are rejected.

Claim(s) 22 is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

- 1.** **Claims 1-21 and 39 are rejected for containing an improper Markush grouping. The materials set forth in the Markush group must belong to a recognized physical or chemical class or to an art-recognized class (see MPEP 706.03(y)).. The members of a proper Markush grouping must share a substantial structural feature disclosed as being essential to that utility (see MPEP 803.02). The generic formula for the instantly claimed Markush groups is as follows:**
- 2. 5,6-dihydro-4-hydroxy-pyran-2-ones; 5,6-dihydro-4-hydroxy-benzopyran-2-ones and 4-hydroxy-cycloalkyl[b]pyran-2-ones. The problem is exacerbated because the terms R₁ through R₁₂ may represent a plethora of substituent groupings as well as saturated and hetero-aryl -type heterocyclic ring systems as well as aryl and aralkyl moieties.**

A proper Markush grouping must share a substantial structural feature disclosed as being essential. The generic formula, as shown above, does not have a substantial core to share with the different Markush groupings. The core is changeable with the different Markush groups within the heterocyclic structure. This changing of the core of the compound adds an instability to the claimed compound. The different and large Markush groupings attached to this changing core only add to the dissimilarity between the different limits of the combined Markush groupings. Thus, the different Markush

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groupings of the aforementioned core rings do not belong to a recognized physical or chemical class or to an art-recognized class as required by MPEP 706.03(y). The improper Markush rejection finds basis in case law, compare *In re Swenson*, 56 USPQ 180; *In re Ruzicka*, 66 USPQ 226; *In re Winnek*, 73 USPQ 225; *In re Harnisch*, 206 USPQ 300, 305 (CCPA 1980). In view of the foregoing, restriction is required to one of the following independent and distinct inventions under 35 U.S.C.121:

GROUP 1:Claims 1-21 and 38- 39 in-part which are N-{[3-(1R or S)-4-hydroxy-5,6-dihydro-2-oxo-6-(R or S)phenethyl-6-propyl-2H-pyran-3-yl]phenyl}-pyridine-2-sulfonamides wherein the 5-position of the pyridine ring represent hydrogen,-CF₃,-NH₂,-CN or any other disclosed substituent that is enabled.Claim 22 is readable thereon.Class 546;Subclass 282.1.

GROUP 11:Claims 1-21 and 38- 39 in-part and Group 1 except that the hetero-aryl moiety represents an optionally substituted imidazolyl moiety.Class 548;Subclass 311.1.

GROUP 111:Claims 1-21 and Group 1, except that the ring moiety represents aryl or aralkyl,both optionally substituted.Class 549;Subclasses 292 and 292.

GROUP IV:Claims 1-21 in-part and Group 1,except that the any other heterocyclic ring is involved.Classes 544;546;548 and 549.

GROUP V:Claims 1-21 in-part and Group 1,except that the lactone is the 4-hydroxy-coumarin or dihydro-benzo-pyran-2-one.Classes 544;546;548; and 549 respectively.

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GROUP V1: Claims 1-21 in-part and Group 1, except that the lactone is 5,6,7,8,9,10-hexahydro-4-hydroxy-2-oxo-cycloocta[b]pyran 3-yl moiety. Classes 540;544;546;548 and 549 respectively.

GROUP V11: Claims 26-29 drawn to a multiple step process for preparing intermediates identified as "X-13A".

GROUP V111: Claims 30-33 drawn to a multiple step process for producing intermediates identified as "HHH-13A".

GROUP 1X: Claims 34-35 drawn to a process for producing intermediates identified as 111-13A".

GROUP X: Claims 36-37 drawn to a process for preparing intermediates identified as "JJJ-13A".

These inventions are distinct from one another as each Group has achieved a separate status in the art, have fields of search which are not coextensive and are capable of supporting separate patents. During a telephone conversation with Martha A. Gammil (Reg. No. 31,820) on Sept. 25, 1997, a provisional election was made with traverse to prosecute the invention of Group 1, claim 1-21, 38 and 39-in-part, claim 22 is readable thereon. Affirmation of this election must be made by applicant in responding to this Office action. Claims 23-37 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. As promised, the undersigned Examiner, expanded the compound species election involving the compound

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of claim 21, found on lines 19-20 of the specification into Group 1 which in the opinion of the undersigned Examiner represents a generic concept.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

REMARKS

After a thorough search, the only reference found was [W0-PCT/US955219] filed May 04, 1995, via Chem. Abstracts, Vol. 124, abst. no. 232,245(1995). applicants' own prior publication. own. Therefore, prior art is not an issue. If applicants' attorney cancels all non-elected subject matter and drafts a new set of claims corresponding to Group 1, this application will be allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan L. Rotman whose telephone number is (703) 308-4698.

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September 26, 1997



ALAN L. ROTMAN
PRIMARY EXAMINER